Remarks/Arguments:

Claims 1, 3-8, 10-18, and 20-26 are pending in the Application.

Claims 1, 11, 16, 18, and 26 are amended herein.

Claim 20 is cancelled herein.

I. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Examiner has rejected Claims 1, 3-8, 10-18, and 20-26 under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement. Examiner contends that "The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Examiner states: "Applicant does not cite to anywhere in the Specification which provides support for the limitation 'does not have any chemical stabilizers'." *See* Office Action, page 2.

Applicant has removed the limitation "does not have any chemical stabilizers" from Claims 1, 3-8, 10-18, and 20-26, by amendment of independent Claims 1, 18, and 26. Accordingly, Applicant respectfully request that the Examiner withdraw the rejection of Claims 1, 3-8, 10-18, and 20-26 as unpatentable under 35 U.S.C. § 112, Second Paragraph.

II. PRIOR REJECTIONS UNDER 35 U.S.C. § 102(b)

Examiner has stated that previous rejection of Claims 1-3, 10, 15-18, 24, and 25 under 35 U.S.C. § 102(b), as being unpatentable over Duffy et al. ("*Duffy*") (U.S. Patent 5,516,793), have been withdrawn "solely for the reason that Duffy does not disclose the exclusion of chemical stabilizers, not withstanding the fact that Applicant does not appear to address how the amendments overcome the prior art " *See* Office Action, page 4.

The Examiner has stated previously that *Duffy* expressly discloses a composition comprising demineralized water, propylene glycol, glycerin, hydroxyethylcellulose, Tween 20, ammonium hydroxide, glycolic acid and ascorbic acid (5% or 10%), having a pH of 3.7 (5%) and 3.8 (10%). The Examiner has also stated that with respect to claim 24, the term "about 15%"

is not defined, as such, the Examiner has read the term "about" to include 10%. *See* Office Action of Dec. 18, 2003, page 2, fourth full paragraph.

Claims 1 and 18 have been amended.

Each of currently-pending independent Claims 1 and 18 have been amended to include the limitation of a non-toxic zinc salt. After such amending, all of the above-rejected, still-pending claims require a composition comprising at least 5.0% (w/v) ascorbic acid in water, a pH of 3.5 to 4.1, and a non-toxic zinc salt. Notwithstanding Applicant's previous arguments that the compositions of *Duffy* would not comprise at least 5.0% (w/v) ascorbic acid in water and a pH of 3.5 to 4.1 in their final admixed form, Applicant respectfully points out that *Duffy* does not disclose such compositions comprising a non-toxic zinc salt. Indeed, nowhere in *Duffy* is the word "zinc" even mentioned. As Duffy does not teach this limitation, Claims 1-3, 10, 15-18, 24, and 25 cannot be anticipated by *Duffy*.

III. PRIOR REJECTIONS UNDER 35 U.S.C. § 103(a)

Examiner has stated that the previous rejection of Claims 1-26 under 35 U.S.C. § 103(a), as being unpatentable over Schinitsky et al. ("*Schinitsky*") (U.S. Patent 4,938,969) in view of Murad ("*Murad*") (U.S. Patent 5,804,594), Herstein ("*Herstein*") (U.S. Patent 5,902,591) and Taylor et al. ("*Taylor*") (U.S. Patent 5,308,621), "is withdrawn solely for the reason that the prior art does not disclose the exclusion of stabilizers." *See* Office Action, page 5.

Claims 2, 9, and 19 have been previously cancelled.

Claim 20 is cancelled herein.

Claims 1, 11, 18, and 26 are amended herein. Claims 1, 18, and 26 have all been amended to include the limitation of a non-toxic zinc salt. After such amending, all of the above-rejected, still-pending claims require a composition comprising at least 5.0% (w/v) ascorbic acid in water, a pH of 3.5 to 4.1, and a non-toxic zinc salt.

The Examiner has noted in a previous office action that Applicant has argued that none of the prior art suggests having a pH of more than 3.5, but that *Herstein* (column 10, lines 6-17) teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. *See* Office Action of Dec. 18, 2003, pages 3 and 4.

The Examiner has repeated such statements in the present Office Action. *See* Office Action, pages 5-6.

In the present Office Action, the Examiner states: "Applicant argues that Murad teaches away from having a pH of more than 3.5 because Murad discloses oral administration, however, Applicant has provided no showing that pH is irrelevant to oral administration. Even in tablets and capsules, pH is a factor which must be accounted for; for example, see Schonmann et al. (US Pat. 4,894,978)."

Regarding pH, Applicant respectfully directs the Examiner to Hawley's Condensed Chemical Dictionary, which defines pH as:

> pH is a value taken to represent the acidity of an aqueous solution, it is defined as the logarithm of the reciprocal of the hydrogen-ion concentration of a solution:
>
> $$pH = \log_{10}(1/[H+])$$

See Hawley's Condensed Chemical Dictionary, Eleventh Ed., I. Sax and R. Lewis, Eds., Van Nostrand Reinhold Co., New York, 1987, page 893. One can see that, as defined above, to possess pH, a composition must be first be a solution, and that such a solution be aqueous, i.e., water-based. As will be described further below, none of *Murad*, *Herstein* and *Taylor* properly describe aqueous solutions of ascorbic acid, and therefore cannot possess pH. Additionally, the reference to pH values and capsules, to which the Examiner points, in Schönmann et al. ("*Schönmann*")(US Pat. 4,894,978) is unclear. Example 1 in *Schönmann*, to which the Examiner points, appears to be directed to a method and/or apparatus for filling capsules with mutually incompatible components which are kept separate inside said capsules. *Schönmann* appears to be suggesting that Vit. B1 is stable in the presence of ascorbic acid, and these two components can be injected together into a capsule. They cannot be injected together with calcium pantothenate, because calcium pantothenate is not stable in the presence of ascorbic acid. Applicant notes that the compositions described in Example 1 are not aqueous solutions, but rather suspensions in Miglyol 812, a commercial triglyceride caprate/succinate used as a carrier. As such, they cannot properly be described as having pH.

In order to establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in

the applied prior art, or in the form of generally available knowledge that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301 (Bd. Pat. App. & Int. 1993); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985). The legal conclusion of obviousness must be supported by facts. See *Graham v. John Deere & Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Where the legal conclusion is not supported by facts, it cannot stand. *Id.* A rejection based on § 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. The patentability of an invention is not to be viewed with hindsight or "viewed after the event." *Goodyear Company v. Ray-O-Vac Company*, 321 U.S. 275, 279, 64 S.Ct. 593, 88 L.Ed. 721 (1944). The proper inquiry is whether bringing them together was obvious and not, whether one of ordinary skill, having the invention before him, would find it obvious through hindsight to construct the invention. Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of the patent Applicants' invention without also providing objective evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. An Examiner's unsupported opinion is not objective evidence.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *See* MPEP § 2143. *See also In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Schinitsky discloses a composition comprising from about 2 to about 20% ascorbic acid, about 1 to about 10% tyrosine, and about 0.5 to about 5% zinc sulfate. *See Schinitsky*, column 2, lines 38-45. Applicant respectfully suggests that *Schinitsky* does not anticipate, disclose, or suggest Applicant's composition as disclosed in Applicant's amended claims 1, 18, and 26 and

the claims depending therefrom, wherein such claims require an aqueous composition of at least 5.0% (w/v) ascorbic acid, a non-toxic zinc salt, and at a pH of 3.5 to 4.1. Applicant respectfully suggests that *Schinitsky* does not disclose or suggest various features of Applicant's claim(s), particularly a composition having a pH of more than 3.5. Examiner's attempts to remedy the deficiencies of *Schinitsky* by combining with three other references, *Murad*, *Herstein*, and *Taylor*, to arrive at Applicant's claimed invention, still fall short of an aqueous composition of at least 5.0% (w/v) ascorbic acid, a non-toxic zinc salt, and at a pH greater than 3.5 as now required by all of the still-pending claims. Why such combination is both unsuggested and deficient will become apparent in the discussion which follows.

Murad discloses a composition comprising at least four components: a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component. *See Murad*, column 3, lines 25-35. Further, *Murad* prefers an embodiment where the composition is administered orally. In fact, all Examples in *Murad* are directed to compositions in either tablet or capsule form. In a preferred *Murad* embodiment, the composition is administered as a tablet or capsule having about 1 mg to 2,000 mg of *Murad* composition. *See Murad*, column 4, lines 39-50. Further, *Murad* discloses that although any suitable route of administration may be employed, oral administration is preferred. *See Murad*, column 8, lines 43-52. Further, all three routes of administration of the *Murad* composition disclosed in the *Murad* examples comprise orally administrated forms such as capsules (*Murad* Example 1), soft gelatin capsules (*Murad* Example 2), and tablets (*Murad* Example 3). *See Murad*, column 10, lines 5-32. Further, *Murad* claim 1 discloses an orally administered pharmaceutical composition comprising the following *Murad* components: a sugar compound; a primary antioxidant component; at least one amino acid component; and at least one transition metal component. *See Murad*, claim 1.

Applicant respectfully suggests that the *Murad* emphasis on oral administration, specifically capsules, soft gelatin capsules, and tablets, *teaches away* from Applicant's composition having a pH of more than 3.5. Applicant also respectfully suggests that since *Murad* is preferably administered orally, pH is not a critical feature of the *Murad* composition and actually teaches away from Applicant's composition, as discussion of pH, being a measure of the hydronium-ion concentration, is limited to solution-based compositions and is not relevant to

the solid-based compositions of *Murad's* tablets and capsules. In fact, pH values have little relevance outside the realm of aqueous-based solutions. Thus, compositions of *Murad* delivered orally in soft gelatin capsules (Example 2) comprising an oil (in which ascorbic acid is only very slightly soluble) are more likely suspensions of ascorbic acid particles, wherein pH again has no relevance.

Herstein discloses a composition comprising two phases. The first *Herstein* phase is a powder phase containing ascorbic acid. The second *Herstein* phase is a liquid emulsion phase containing a stabilizing effective amount of an organoclay composition. *See Herstein*, column 2, line 65 - column 3, line 6. *Herstein* discloses in great detail the two phases. *Herstein* discloses that the liquid phase comprises an emulsifier that can be selected from various emulsifiers. *See Herstein*, column 4, line 31 - column 6, line 19. *Herstein* maintains that the pH of the combined two-phase composition is preferably maintained within a pH range of 3.5-4.1. Applicant respectfully points out that emulsions are not solutions. Applicant further respectfully points out that the organoclays described in *Herstein* comprise amine salts that can be expected to complex the ascorbate anion. Thus, while such formulations of *Herstein* are novel in their use of such organoclays to stabilize the ascorbate anion, much of the ascorbic acid has been taken out of the liquid phase when it complexes with the organoclay. Applicant notes that *Herstein* provides no empirical evidence for his above-described claim of 82% protonation.

Taylor discloses the transdermal delivery of micro-sized particles of ascorbic acid. Such micro-sized particles of ascorbic acid are "predominately sized below 20 microns [μm]. More preferably they are predominately in the range of from 2-10 microns." *See Taylor*, column 1, lines 52-55. Such particles are dispersed in a carrier such that "the portion of ascorbic acid [as particulates] in solution will be less than 0.1% by weight of the composition." *See Taylor*, column 1, lines 59-60. A number of suitable non-aqueous carriers are listed (column 2, lines 20-26) and it is stated that "[p]referably the carrier is essentially water free containing less than about 0.5% by weight water." *See Taylor*, column 2, lines 35-37. Applicant points out that when water is present in only 0.5% by weight, it is not a solvent, but rather a solute (again, having no pH relevance). The only similarity this reference has with the present Application is the presence of ascorbic acid, albeit in a particulate (solid) form.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify any of the above-mentioned references, either in the references themselves, or in the knowledge of one of ordinary skill in the art at the time the invention was made. *Murad*, *Herstein*, and *Taylor* all teach solid or multiphase solid/liquid compositions (i.e., emulsions). The dissimilar nature, in terms of their phase of matter) argues against their being combined with *Schinitsky*. Furthermore, even if they were combined, one of ordinary skill in the art would not arrive at the presently claimed invention because none of these references truly teaches an ascorbic acid composition with a pH of 3.5 to 4.1, as the Examiner contends. As such, a rejection of claims 1, 3-8, 10-18, and 21-26 under 35 U.S.C. § 103(a) as being unpatentable over *Schinitsky* in view of *Murad*, *Herstein* and *Taylor* cannot properly be made.

IV. CONCLUSION

As a result of the foregoing, it is asserted by Applicant that the Claims in the Application are now in a condition for allowance, and respectfully request an early allowance of such Claims.

Since new claims have not been added, no additional filing fees are believed to be due. It is believed that no further fees are due. However, the Director is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C. (referencing number 41758-P001P1C2X1).

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at (214) 745-5710.

Respectfully submitted,
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